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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,446	09/08/2000	David E. Edgren	ARC 2762C1	1540

30766 7590 07/14/2005

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HOUSTON, TX 77069

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/657,446

Applicant(s)

EDGREN ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46, 48, 51 and 53-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46, 48, 51 and 53-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration, request for extension of time, request for change of address and remarks, all filed 04/28/05. Examiner thanks applicants for pointing to the support for the previous amendment in the specification.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 46, 48, 51, 53-58 and 60 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5,558,879).

Response to Arguments

Applicants argue that Chen does not disclose a coated layer that is made up of hydrophobic and hydrophilic polymers and that Chen does not anticipate claim 46 and the claims 48, 51 and 53-58 dependent on claim 46 and claim 60, which is a method of delivering the dosage form of claim 46.

3. Applicants' arguments filed 04/28/2005 have been fully considered but they are not persuasive.

Contrary to applicants' assertion, it is respectfully noted that Chen discloses inner coating layer that consists of water insoluble pharmaceutically acceptable polymer and pharmaceutically acceptable water-soluble polymer (abstract). The hydrophilic polymer of the claim reads on the water-soluble polymer of the prior art; similarly, the hydrophobic polymer of the claim reads on the water insoluble polymer of the prior art. Ethyl cellulose is the preferred water insoluble polymer of Chen (column 5, line 12 and lines 1-11).

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4. Claims 46, 48, 51 and 53-60 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bartoo et al. (US 4,743,248).

Response to Arguments

Applicants state that Examiner asserts that “the scope of the instant claim 46 is a possibility between hydrophobic substance and hydrophilic substance and Bartoo does not have to disclose both. Bartoo only has to disclose one.” Applicants then state that Examiner admits that Bartoo does not disclose an inner polymeric layer that is made up of hydrophobic and hydrophilic polymers and as such Bartoo does not anticipate claim 46 and the claims dependent therefrom.

5. Applicants' arguments filed 04/28/05 have been fully considered but they are not persuasive.

The statement applicants refer to is a response to applicants' argument and was in reference to applicants statement of enteric polymer. Bartoo clearly discloses an inner polymeric coating layer that is made up of hydrophobic polymer and hydrophilic polymer (see Example 1 at column 8, lines 49-52). Polyethylene glycol is hydrophilic; cellulose acetate is hydrophobic and hydroxypropylmethylcellulose phthalate is also water insoluble and exhibits pH sensitive solubility and are referred to as entero-soluble. Therefore, the inner layer of Bartoo, at least in Example 1 is made up of water insoluble and water-soluble polymers.

No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Upon further review of the specification for the support for the previous amendment, it is noted that at page 11, lines 2 and 3, ethyl cellulose is listed as an example of hydrophilic polymer. Applicants are respectfully requested to comment or correct.


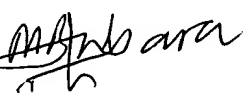
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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